IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSSETS

JESSICA FOUNTAINE,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NUMBER:**
	)	
BAYER HEALTHCARE PHARMACEUTICALS, INC., BAYER PHARMA AG, and BAYER OY	)	_____
	)	
	)	**JURY TRIAL DEMANDED**
Defendants.	)	

COMPLAINT

COMES NOW, Plaintiff Jessica Fountaine, by and through the undersigned counsel, hereby allege against Bayer Healthcare Pharmaceuticals, Inc., Bayer Oy and Bayer Pharma AG the following:

PARTIES

1. At all relevant times hereto, Plaintiff Jessica Fountaine was a citizen and resident of Essex County, Massachusetts and used Defendants' intrauterine contraceptive system, Mirena®.

2. Defendant Bayer Healthcare Pharmaceuticals Inc., is, and at all times relevant was, a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000. Pursuant to MDL Order, dated July 17, 2013, Document 225, this Defendant may be served with process, via **certified mail**, upon the following representative:

SOP Department
Corporation Service Company
Suite 400
2711 Centerville Road
Wilmington, DE 19808

3. Defendant, BAYER OY is a foreign company that is organized and exists under the laws of Finland with its principal place of business at Pansiontie 47 20210 Turku, Finland. Defendant, Bayer Oy may be served with process via **registered mail**, no less than seven (7) calendar days after mailing of service upon Bayer Healthcare Pharmaceuticals, Inc., at:

Bayer Oy
Legal Department
Pansiontie 47 / P.O. Box 415
20101 TUKRKU
FINLAND

4. Defendant, BAYER PHARMA AG is a foreign company domiciled in Germany with its principal place of business in Wuppertal, Germany. Defendant, Bayer Pharma AG may be served with process via **registered mail**, no less than (7) calendar days after mailing of service upon Bayer Healthcare Pharmaceuticals, Inc., at:

Bayer Pharma AG
Attn: Eva Gardyan-Eisenlohr
General Counsel
Muellerstrasse 178
13353 Berlin
GERMANY

5. Defendants transacted and conducted business in the State of Massachusetts and have derived substantial revenue from interstate commerce.

6. Upon information and belief, at all relevant times, Defendants expected or should have expected that its acts would have consequences within the United States of America, particularly Massachusetts, and derived substantial revenue from interstate commerce.

7. Upon information and belief, Defendants were in the business of designing, researching, manufacturing, testing, advertising, promoting, marketing, selling, and distributing Mirena, into interstate commerce throughout the United States, either directly or indirectly through third parties, subsidiaries or related entities, as an intrauterine contraceptive device or system.

8. Defendant, Bayer Healthcare Pharmaceuticals, Inc., admits that on April 4, 2007, as part of a corporate acquisition, the name of Berlex, Inc. was changed to Bayer Healthcare Pharmaceuticals, Inc.

9. Defendant, Bayer Healthcare Pharmaceuticals Inc., admits that, at certain times, it designed, developed, marketed, distributed, advertised, promoted, and/or sold Mirena in the United States.

10. Defendant Bayer Healthcare Pharmaceuticals, Inc. is the holder of the approved New Drug Application ("NDA") for the contraceptive device Mirena.

11. Defendant, Bayer Oy, admits that it designed, developed, researched, manufactured, and tested all Mirena sold by Bayer Healthcare Pharmaceuticals, Inc. in the United States.

12. Defendant, Bayer Oy, admits that it sold Mirena directly to Bayer Healthcare Pharmaceuticals, Inc. until September 1, 2008. After September 1, 2008, Bayer Oy sold Mirena to Bayer Pharma AG, which resold the product to Bayer Healthcare Pharmaceuticals, Inc.

13. Defendant, Bayer Pharma AG admits that it designed, developed, and researched all Mirena sold by Bayer Healthcare Pharmaceuticals, Inc. in the United States exclusively from Bayer Oy and resold the product to Bayer Healthcare Pharmaceuticals, Inc.

14. Defendant, Bayer Healthcare Pharmaceuticals, Inc., admits that prior to September

1, 2008, it and its predecessors purchased all Mirena sold in the United States from Bayer Oy and its predecessors. After September 1, 2008, Bayer Healthcare Pharmaceuticals, Inc. purchased all Mirena sold in the United States from Bayer Pharma AG, which purchased the product from Bayer Oy.

15. At all times alleged herein, "Defendants" includes and included any and all parents, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives and any and all other persons acting on their behalf.

JURISDICTION

16. Jurisdiction is conferred on this Court by the provisions of 28 U.S.C. § 1332(a), et seq., by virtue of diversity of citizenship where the matter in controversy, exclusive of interest and cost, exceeds $75,000.00.

I. FACTS

17. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth herein, and further allege as follows:

18. Mirena® is an intrauterine contraceptive system made of flexible plastic that is inserted by a healthcare provider during an office visit. Mirena® is a T-shaped polyethylene frame with a steroid reservoir that releases levonorgestrel, a prescription medication used as a contraceptive.

19. The federal Food and Drug Administration ("FDA") approved Defendants' New Drug Application for Mirena® in December 2000. Today, more than 2 million women in the United States use Mirena®. It has been used by more than 15 million women worldwide.

20. The system releases levonorgestrel, a synthetic progestogen, directly into the uterus

for birth control. Defendants admit "[i]t is not known exactly how Mirena® works," but provide that Mirena® may thicken cervical mucus, thin the uterine lining, inhibit sperm movement and reduce sperm survival to prevent pregnancy.

21. The Mirena® intrauterine system (IUS) is designed to be placed within seven (7) days of the first day of menstruation and approved to remain in the uterus for up to five years. If continued used is desired after five years, the old system must be discarded and a new one inserted.

22. The package labeling recommends that Mirena® be used in women who have had at least one child.

23. The Mirena® label does not warn about spontaneous migration of the IUS, but only states that migration may occur if the uterus is perforated during insertion.

24. The Mirena® label also describes perforation as an "uncommon" event, despite the numerous women who have suffered migration and perforation post-insertion, clearly demonstrating this assertion to be false.

25. Defendants have a history of overstating the efficacy of Mirena® while understating the potential safety concerns.

26. In or around December 2009, Defendants were contacted by the Department of Health and Human Services' Division of Drug Marketing, Advertising, and Communications ("DDMAC") regarding a consumer-directed program entitled "Mirena Simple Style Statements Program," a live presentation designed for "busy moms." The Simple Style program was presented in a consumer's home or other private setting by a representative from "Mom Central", a social networking internet site, and Ms. Barb Dehn, a nurse practitioner, in partnership with Defendants.

27. This Simple Style program represented that Mirena® use would increase the level

of intimacy, romance and emotional satisfaction between sexual partners. DDMAC determined these claims were unsubstantiated and, in fact, pointed out that Mirena®'s package insert states that at least 5% of clinical trial patients reported a decreased libido after use.

28. The Simple Style program script also intimated that Mirena® use can help patients "look and feel great." Again, DDMAC noted these claims were unsubstantiated and that Mirena® can cause a number of side effects, including weight gain, acne, and breast pain or tenderness.

29. The portion of the Simple Style script regarding risks omitted information about serious conditions, including susceptibility to infections and the possibility of miscarriage in a woman who becomes pregnant on Mirena®.

30. Finally, Defendants falsely claimed that its program required no compliance with a monthly routine.

31. The Defendants' concealment of known defects from the FDA, Plaintiff, and the medical community constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

32. Plaintiff was not aware of, and could not in the exercise of reasonable care have discovered, the existence of the defect in the Mirena® IUS, without considerable television and internet information disclosed by third parties.

33. Defendants are estopped from relying on the statute of limitations defense because Defendants concealed the increased risk of embedment and perforation with ordinary and intended use, leading to major surgery for the removal of the IUS. Instead of disclosing the risks, Defendants continue to represent its product as safe for its intended use, and has kept it on the market without change in the labeling and warnings.

34. Plaintiff Jessica Fountaine had the Mirena® IUS inserted on March 3, 2009 at

Women's Health Care in Newburyport, Massachusetts. The Mirena® IUS insertion was uncomplicated and was properly placed.

35. On May 12, 2010, Plaintiff Jessica Fountaine returned to Women's Health Care. Dr. Margaret Rawson was unable to visualize the Mirena® IUD strings and ordered an ultrasound. The ultrasound confirmed that the IUD was in place.

36. On December 3, 1010, Plaintiff presented at Women's Health Care complaining of vaginal bleeding. Dr. Mary Chang informed Plaintiff that she was six weeks pregnant.

37. On December 13, 2010, Plaintiff underwent a legal abortion. There was no IUD mentioned on the fetal ultrasound. Both Plaintiff and Dr. Chang assumed the IUD had fallen out.

38. Plaintiff Jessica Fountaine had another Mirena® IUS inserted on March 2, 2011 at Coastal Medical Association in Newburyport, Massachusetts. The Mirena® IUS insertion was uncomplicated and was properly placed.

39. Plaintiff Jessica Fountaine was anxious about the Mirena® IUD falling out again and returned to Coastal Medical Association on April 6, 2011 to have the IUD checked. Patrice Kellogg, NP confirmed the IUD strings were present. Plaintiff returned to Coastal Medical Association on May 18, 2011 and December 15, 2011. Both times the IUD strings were present.

40. On June 11, 2012 Plaintiff presented at Anna Jaques Hospital Emergency Department complaining of abdominal pain. Dr. Robin Gross treated Plaintiff.

41. On June 12, 2012 Plaintiff had an upper GI Series performed by Dr. Melissa Maloney at Coastal Medical Association in Newburyport, Massachusetts. Dr. Maloney noted on the preliminary view of the abdomen that there was an IUD overlying the upper left side of the sacrum. Dr. Maloney also confirmed that there was an IUD in the uterus. Dr. Maloney noted that "that there are two IUDs within the pelvis."

42. On June 27, 2012 Plaintiff Jessica Fountaine was evaluated for a retained IUD at Massachusetts General Hospital in Boston, Massachusetts by Dr. Erik Clinton. The IUD was seen in the abdominal cavity.

43. On July 27, 2012 Plaintiff Jessica Fountaine was required to undergo surgical removal of the migrated and retained Mirena® IUS by Dr. Erik Clinton at Massachusetts General Hospital in Boston, Massachusetts.

II. COUNTS

COUNT I
NEGLIGENT MANUFACTURING

44. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

45. Defendants were engaged in the business of manufacturing Mirena® in the State of Massachusetts.

46. The Mirena® was negligently manufactured by Defendants in that when it left the hands of Defendants, the Mirena® deviated from product specifications, applicable federal requirements, and industry standards for these medical devices, rendering the product unreasonably dangerous.

47. Defendants introduced a product into the stream of commerce which is dangerous and unsafe in that the harm of Mirena® outweighs any benefit derived therefrom. The unreasonably dangerous nature of Mirena® was the proximate cause of serious harm to Plaintiff JESSICA FOUNTAINE.

48. A reasonable manufacturer would or should have known of the manufacturing defects and that the risks created the defects are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that

compensates in whole or part for the increased risk.

49. As a direct and proximate result of Plaintiff JESSICA FOUNTAINE'S use of Mirena®, she was forced to undergo surgical removal of the embedded Mirena® IUS, developed severe pain from the device, and had to undergo numerous procedures.

50. Defendants knew and, in fact, advertised and promoted the use of Mirena® despite its failure to test or otherwise determine the safety and efficacy of such use. As a direct and proximate result of the Defendants' negligence, physicians began commonly prescribing this product as safe and effective.

51. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff JESSICA FOUNTAINE suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT II
NEGLIGENT DESIGN

52. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

53. The Mirena® manufactured, designed, formulated, tested, created, made, constructed, assembled, marketed, advertised, distributed and sold by Defendants was defective in design or formulation in that Defendants knew or should have known that the product design made the foreseeable risks of the product exceed the benefits, and it was more dangerous than an ordinary consumer would expect.

54. Defendants negligently failed or improperly weighed the likelihood of danger posed by this design against the feasibility, cost, and adverse consequences of an alternative design.

55. As a direct and proximate cause of Plaintiff's use of Mirena®, she was forced to undergo surgical removal of the Mirena® IUS.

56. Defendants knew or should have known that physicians and other healthcare providers began commonly prescribing this product as a safe and effective contraceptive despite its lack of efficacy and potential for serious permanent side effects.

57. There are contraceptives on the market with safer alternative designs in that they provide equal or greater efficacy and far less risk.

58. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff JESSICA FOUNTAINE suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT III
NEGLIGENT FAILURE TO WARN

59. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

60. The Defendants' labeling failed to adequately warn consumers and prescribers of, among other things, the risk of embedment and migration of the Mirena® post-insertion, uterine perforation post-insertion, surgical removal, or the possibility that device complications such as

migration and perforation may cause abscesses, infections, require surgery for removal and/or may necessitate hysterectomy, oophorectomy, and other complications.

61. Defendants manufactured, designed, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, distributed, sold and otherwise released into the stream of commerce the pharmaceutical, Mirena®, and in the course of the same, directly advertised or marketed the product to consumers or persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of Mirena®.

62. Mirena® was under the exclusive control of Defendants and Defendants knew or should have known that the Mirena® was unaccompanied by appropriate warnings regarding all of the risks associated with its use. The warnings given did not accurately reflect the risk, incidence, symptoms, scope or severity of such injuries to the consumer or physicians. The promotional activities of Defendants further diluted or minimized the warnings given with the product.

63. Defendants downplayed the serious and dangerous side effects of Mirena® to encourage sales of the product; consequently, Defendants placed their profits above customer safety.

64. Mirena® was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert the Plaintiff to the dangerous risks and reactions associated with it. Even though Defendants knew or should have known of the risks associated with Mirena®, they still failed to provide warnings that accurately reflected the signs, symptoms, incident, scope, or severity of the risks associated with the product. Defendants knew and, in fact, advertised and promoted the use of Mirena® despite its failure to test or otherwise

determine the safety and efficacy of such use. As a direct and proximate result of the Defendants' advertising and widespread promotional activity, physicians began commonly prescribing this product as safe and effective.

65. Plaintiff JESSICA FOUNTAINE could not have discovered any defect in Mirena® through the exercise of reasonable care.

66. Defendants, as a manufacturers of pharmaceutical drugs, are held to the level of knowledge of an expert in the field and, further, Defendants had knowledge of the dangerous risks and side effects of Mirena®.

67. Plaintiff JESSICA FOUNTAINE did not have the same knowledge as Defendants and no adequate warning was communicated to her physician(s).

68. Defendants had a continuing duty to warn consumers, including Plaintiff JESSICA FOUNTAINE and her physicians, and the medical community of the dangers associated with Mirena® and by negligently and/or wantonly failing to adequately warn of the dangers associated with its use, Defendants breached their duty.

69. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff JESSICA FOUNTAINE suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT IV
NEGLIGENCE

70. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully

set forth, and further alleges as follows:

71. Upon information and belief, Defendants failed to use reasonable care in designing Mirena® in that they:

a. failed to properly and thoroughly test Mirena® before releasing the drug to market;

b. failed to properly and thoroughly analyze the data resulting from the premarketing tests of Mirena®;

c. failed to conduct sufficient post-market testing and surveillance of Mirena®;

72. A reasonable manufacturer would or should have known that the risks created by Mirena® are unreasonably greater than that of other contraceptives and that Mirena® has no clinical benefit over such other contraceptives that compensates in whole or part for the increased risk.

73. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff JESSICA FOUNTAINE suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT V
BREACH OF IMPLIED WARRANTY
OF MERCHANTABILITY

74. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

75. Defendants manufactured, promoted, distributed and sold Mirena® as safe for use

by the public at large, including Plaintiff JESSICA FOUNTAINE, who purchased Mirena®. Defendants knew the use for which Mirena® was intended and impliedly warranted the product to be of merchantable quality, safe and fit for the ordinary purposes for which the product is used.

76. Plaintiff JESSICA FOUNTAINE reasonably relied on the skill and judgment of Defendants, and as such the implied warranty, in using Mirena®.

77. Contrary to same, Mirena® was not fit for the ordinary purposes for its intended use, because it is unreasonably dangerous and unfit for the ordinary purpose for which it was used, and hence, defective.

78. The Mirena® was not fit for the ordinary purposes for which is was intended to be used because it was defectively manufactured and did not conform to the design standards, making the Mirena® IUD unreasonably dangerous and unfit for its ordinary purposes.

79. The Mirena® was defectively designed in that its design makes it dangerous to an extent beyond the expectations of the ordinary consumer and user with common knowledge of the product's uses and characteristics.

80. The Mirena® was unreasonably dangers and unfit for its ordinary purposes because the product labeling failed to adequately warn consumers and prescribers of, among other things, the risk of embedment and migration of the product post-insertion, uterine perforation post-insertion, surgical removal, or the possibility that device complications such as migration and perforation may cause abscesses, infections, require surgery for removal and/or may necessitate hysterectomy, oophorectomy, and other complications.

81. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff JESSICA FOUNTAINE suffered profound injuries, required and

continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

COUNT VI
BREACH OF EXPRESS WARRANTY

82. Plaintiff incorporates by reference all other paragraphs of this complaint as if fully set forth, and further alleges as follows:

83. The aforementioned manufacturing, designing, distributing, marketing, and promoting of Mirena® was expressly warranted to be safe by Defendants for Plaintiff JESSICA FOUNTAINE and members of the public generally. At the time of the making of these express warranties, Defendants had knowledge of the foreseeable purposes for which Mirena® was to be used and Defendants warranted Mirena® to be in all respects, safe, effective and fit for the ordinary purposes for which such the product is used.

84. Mirena® does not conform to these express warranties and representations because Mirena® is not fit for the ordinary purposes for which such product is used and may produce serious side effects.

85. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, Plaintiff JESSICA FOUNTAINE suffered profound injuries, required and continues to require medical treatment, and incurred and continues to incur medical and hospital expenses.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorney's fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

PRAYER FOR RELIEF

Plaintiff demands judgment against Defendants for compensatory damages, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems appropriate pursuant to the common law and statutory law.

Dated this 15th day of June, 2015.

Respectfully submitted,

/s/ Paula S. Bliss
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